MAY 3 0 2003

K030976

510(k) Summary
for the Life-Shield Products, Inc.
CAREO Retractable Safety Syringe
(per 21CFR807.92)

1. SPONSOR

Life-Shield Products, Inc.
3F, No. 10, Wuchiuan 7th Rd
Wugu Shiang
Taipei 248
Taiwan, ROC

Contact Person: Mr. Eric Shih, President
Telephone: 011-866-2-2299-6033

Date Prepared: May 13, 2003

2. DEVICE NAME

Proprietary Name:	CAREO Retractable Safety Syringe
Common/Usual Name:	Hypodermic Syringe (with needle)
Classification Name:	Piston syringe
	Hypodermic single lumen needle

3. PREDICATE DEVICE

- SECUREGARD® Retractable Safety Syringe (K012121)

4. DEVICE DESCRIPTION

The Life-Shield Products, Inc., CAREO Retractable Safety Syringe is a sterile, single-use and disposable, 3 mL piston syringe, provided with a permanently attached needle in eight product configurations. The CAREO Retractable Safety Syringe is similar in appearance, size, materials, operation, and purpose to the cited predicate device and other conventional single-use, sterile, disposable syringes.

5. INTENDED USE

The CAREO Retractable Safety Syringe is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient. The syringe should not be used for blood collection.

The CAREO Retractable Safety Syringe aids in the prevention of needlestick injuries. In addition, when the user breaks the plunger, the CAREO Retractable Safety Syringe reduces the possibility of syringe reuse.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Life-Shield Products, Inc., makes a claim of substantial equivalence of the CAREO Retractable Safety Syringe to the SECUREGARD® Retractable Safety Syringe (K012121) based on similarities in intended use, design, technological and operational characteristics. Both are indicated for injecting fluids into the body, while helping to reduce the risk of sharps injuries. Both syringes are piston syringes that use permanently attached single lumen hypodermic needles. Both syringes are provided sterile, single-use, and disposable. Both syringes require the user to manually retract the needle-plunger into the syringe barrel, break off the plunger rod, and discard the pieces.

7. TESTING

Testing provided in this premarket notification includes biocompatibility, packaging integrity, standards conformity, and simulated use testing. Side-by-side testing of the CAREO Retractable Safety Syringe and the SECUREGARD® Retractable Safety Syringe shows that the two products are equivalent. Simulated use testing using 500 syringes demonstrates that the CAREO Retractable Safety Syringe performs according to specification. Testing also supports the claimed Indications for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Life-Shield Products, Incorporated
C/O Ms. Rosina Robinson, RN, Med, RAC
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K030976
Trade/Device Name: Life-Shield Products, Inc., CAREO Retractable Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 27, 2003
Received: March 28, 2003

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030976

Device Name: Life-Shield Products, Inc., CAREO Retractable Safety Syringe

Indications for Use:

The CAREO Retractable Safety Syringe is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient. The syringe should not be used for blood collection.

The CAREO Retractable Safety Syringe aids in the prevention of needlestick injuries. In addition, when the user breaks the plunger, the CAREO Retractable Safety Syringe reduces the possibility of syringe reuse.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucinotta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030976

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)